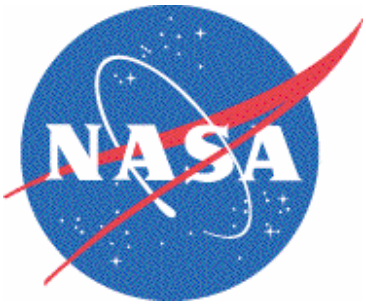

Langley Research Center

LPR 7100.10

Effective Date: June 20, 2005

Expiration Date: June 9, 2010

PROTECTION OF HUMAN RESEARCH SUBJECTS

National Aeronautics and Space Administration

Responsible Office: Safety and Mission Assurance Office

PREFACE

P.1 Purpose

P.1.1 This document describes how Langley Research Center (LaRC) will:

- Implement Federal and NASA regulations covering research involving human subjects
- Ensure the safety, health, and welfare of human test subjects associated with research conducted for, with, by, or at Langley Research Center.

P.2 Applicability

P.2.1 This document applies to research involving human subjects that meets any of the following conditions:

- Is funded by Langley Research Center.
- Involves Langley Research Center personnel, either civil servant or contractor, in their official, professional role.
- Is conducted at Langley Research Center.
- Utilizes Langley Research Center's equipment or facilities.

P.3 Authority

a. 14 CFR 1230 – Protection of Human Subjects

P.4 References

a. NPD 7100.8, "Protection of Human Research Subjects"
b. NPR 7100.1, "Protection of Human Research Subjects"
c. LAPD 1150.2, "Boards, Panels, Committees, Councils, and Teams"
d. Langley Research Center Employee Safety Pocket Guide

P.5 Cancellation

None

original signed on file

Roy D. Bridges, Jr.
Director

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Section **Page**

1. Introduction

1.1 This document describes how Langley Research Center (LaRC) will protect the safety, health, and welfare of human research subjects and implement the regulations and policies prescribed by:

- 14 CFR 1230 – Protection of Human Subjects.
- NPD 7100.8 – Protection of Human Research Subjects.
- NPR 7100.1 – Protection of Human Research Subjects.

1.2 **The contents of this document complement the information contained in 14 CFR 1230, NPD 7100.8, and NPR 7100.1. This document cannot be used in a stand-alone manner. Parties associated with research involving human subjects must refer to and understand the contents of all these governing documents in order to fulfill their responsibilities.**

2. Principles

2.1 LaRC will apply the following principles to research involving human subjects:

2.1.1 Any person who participates as a test subject in human subject research will do so on a voluntary basis. No coercion will be used. Before agreeing to participate, test subjects will be given a description and explanation of the test, their role, their risks, and the potential benefits of the research. The description and explanation will be presented in language and terminology that the test subject can understand.

2.1.2 Research tests involving human subjects will not be conducted unless the risks are reasonable in relation to the accumulated benefits to the test subject and to the importance of the knowledge to be gained.

2.1.3 Selection of test subjects will be equitable and reasonable. The burden and benefits of the research will be fairly distributed.

2.1.4 The Principal Investigator (PI) is responsible for establishing and conducting tests in a manner that protects the safety, health, and welfare of the test subjects.

2.1.5 Private information about test subjects will be protected and will not be released without prior written consent of the test subject.

2.1.6 An Institutional Review Board (IRB) will provide independent review, approval, and oversight of all research involving human subjects.

2.1.7 Research involving human subjects will be conducted in accordance with:

- 14 CFR 1230 – Protection of Human Subjects
- NPD 7100.8 – Protection of Human Research Subjects
- NPR 7100.1 – Protection of Human Research Subjects

2.1.8 The objective of LaRC is to avoid loss of life, personal injury and illness, property loss or damage, or environmental harm and to ensure safe and healthful conditions for all parties involved in its research activities. While conducting research involving human test subjects, LaRC will protect the test subjects from harm or injury (physical, psychological, social, or economic).

2.1.9 All persons participating in research involving human subjects are required to report any potential hazards or any unanticipated problems encountered during the research.

2.1.10 If unsafe conditions or work practices present imminent danger to personnel or property during the conduct of research involving human subjects, all parties involved are vested with the right and obligation to promptly stop the work and report the condition to the PI, the responsible supervisor, or the LaRC Safety Office.

3. Key Responsibilities

3.1 All parties involved with human subject research are responsible for:

- Safely conducting the research.
- Following approved procedures.
- Reporting safety hazards to the PI, their supervisor, or the LaRC Safety Office.
- Exercising the stop-work authority, if they detect an imminent danger to personnel or property.

3.2 Principal Investigators (PIs) are responsible for:

- Following the provisions of 14 CFR 1230, NPD 7100.8, NPR 7100.1, and this LPR.
- Designing and conducting research experiments in a manner that safeguards the safety, health, and welfare of the test subjects.
- Reporting accidents, unexpected events, close calls, and safety concerns to the LaRC Safety Office.
- Obtaining the review and approval of the LaRC IRB before commencing any experiments involving human research subjects or implementing changes or modifications to previously approved research.

3.3 LaRC line managers are responsible for assuring that:

- PIs are adequately trained and qualified to perform research involving human subjects.
- PIs follow applicable regulations, policies, and procedures.
- The LaRC IRB is properly staffed and has any other resources needed to comply with its responsibilities.
- Federal funds are not expended for research involving human subjects unless the provisions of 14 CFR 1230, NPD 7100.8, and NPR 7100.1 are met.

3.4 Test Subjects are responsible for:

- Reading and signing the informed consent statement after requesting clarification of anything they do not fully understand.
- Alerting the PI should any situation arise which may affect their ability to participate in the study.
- Reporting accidents, illness, changes in their health, close calls, and safety or health concerns.
- Initiating the stoppage of work in case of imminent danger.

3.5 Persons who prepare statements of work for research involving human subjects are responsible for:

- Including requirements mandating adherence to applicable Federal regulations (14 CFR 1230, NPD 7100.8, NPR 7100.1, and this LPR).
- Transmitting a copy of the statement of work to the LaRC IRB Secretary.
- Forwarding a copy of the performing institution’s certification to the LaRC IRB Secretary.

3.6 Persons who review and recommend acceptance of unsolicited proposals for research involving human subjects are responsible for:

- Ensuring that they contain a requirement that mandates adherence to applicable Federal regulations (14 CFR 1230, NPD 7100.8, and NPR 7100.1) or a certification from the proposing institution indicating that the proposed research has been reviewed and approved by a Federally-approved IRB.
- Providing a copy of unsolicited proposals that are recommended for funding to the LaRC IRB Secretary.
- Sending a copy of the performing institution's certification to the LaRC IRB Secretary.

3.7 The LaRC IRB is responsible for providing review, approval, and oversight of research experiments involving human test subjects to ensure that: (a) the safety, health, and welfare of human subjects are adequately protected and (b) applicable regulations, policies, and practices are followed.

3.8 LaRC Safety Office is responsible for:

- Notifying LaRC and NASA Headquarters officials of accidents and unexpected events in accordance with established policies.
- Forwarding reports of unexpected events to the LaRC IRB Chairperson.
- Assuring that adequate actions are taken to investigate and address accidents, safety hazards, and safety or health concerns.

4. Conducting Research Involving Human Subjects

4.1 Authority and Obligation To Stop A Test

4.1.1 If unsafe conditions present an imminent danger to any person or equipment, all associated personnel, including test subjects, are vested with the right and obligation to stop the testing.

4.1.2 When anyone involved in a test senses an imminent hazard, they shall notify the PI (or the person in charge of the test) of the danger and declare they are exercising the stop work authority. Testing shall promptly be halted. Then the hazard shall be assessed and appropriate corrective actions taken.

4.1.3 All parties associated with the test shall comply with and support this policy.

4.2 Application for IRB Review

4.2.1 The PI shall prepare an Application for IRB Review of Human Subject Research and submit it electronically to the LaRC IRB Secretary. (See LAPD 1150.2, "Boards, Panels, Committees, Councils, and Teams," for identification of the IRB Secretary.) An outline of the Application is shown in Appendix A. An electronic copy can be obtained from the LaRC IRB Chairperson or Secretary.

4.2.2 Proposed research involving human subjects and any proposed changes or modifications to previously approved research involving human subjects must be reviewed and approved by the LaRC IRB before the PI can involve test subjects in the research activities or implement changes.

4.3 Informed Consent

4.3.1 Participation as a test subject in human subject research will be strictly on a voluntary basis. No coercion will be used. Research test subjects will be provided an Informed Consent Statement that thoroughly and completely discloses all relevant risks and benefits associated with their involvement in the research. Prospective test subjects shall read and sign the Informed Consent Statement prior to their participation as a test subject.

4.3.2 It is LaRC policy to inform and obtain documented consent from test subjects before their involvement in any research activity.

4.3.3 The PI shall prepare a proposed Informed Consent Statement. The Informed Consent Statement shall be clearly written and use language and terminology that the test subjects can understand.

4.3.4 The required contents of the Informed Consent Statement are contained in 14 CFR 1230 and NPR 7100.1. Appendix B sets forth a summary of these requirements. Informed Consent Statements used for research involving LaRC personnel, facilities, or

equipment shall also contain the required text noted in Appendix B. If necessary, this required text may be tailored to the proposed research.

4.3.5 The proposed Informed Consent Statement shall be submitted to the IRB Secretary along with the Application for IRB Review of Human Subject Research.

4.3.6 To obtain Informed Consent, PIs shall:

- Provide a complete copy of the Informed Consent Statement to the prospective test subject for his or her permanent records.
- Allow the prospective test subject time to read the statement.
- Discuss the test, the test subject's role in the test, the risks, and the benefits with the prospective test subject.
- Give the prospective test subject an opportunity to ask questions and provide answers to any questions asked.
- Permit the test subject to sign a copy of the Informed Consent Statement.

4.4 Privacy of Data

4.4.1 NASA and the PI will protect all private information obtained during the course of research involving human test subjects. The PI shall develop and implement a plan to: (a) protect the private information associated with test subjects; and (b) prevent the improper disclosure of private information about any test subject without the test subject's previous written permission. Provisions shall be made to protect private information that is stored electronically. The PI shall maintain and retain all records associated with research activities for at least 3 years after completion of the research.

4.5 Pre-Test and/or Post Test Screening

4.5.1 The PI shall decide whether pre-test and/or post-test screenings are needed to: (a) assure the validity of experimental results; or (b) protect the health and safety of the test subjects.

4.5.2 When screenings are employed, the PI shall determine whether to use questionnaires, debriefings, or medical examinations. The PI shall implement the appropriate screening methodology.

4.6 Appropriate Monitoring or Medical Coverage

4.6.1 The PI shall determine whether:

- The health or medical condition of test subjects will be monitored during the course of the research.
- Special medical coverage is needed to provide quicker than normal response to potential injuries or health problems.

4.6.2 The PI shall take steps to implement the health monitoring and medical coverage determined to be appropriate.

4.7 Responding To and Reporting Unexpected Events

4.7.1 Personnel involved with human subject research shall promptly respond to and subsequently report the following unexpected events:

- Accidents involving death, injury, property damage, or environmental damage.
- Death, illness, or unforeseen medical problems of a test subject.
- Any change in a test subject's health or the test environment that could forecast a medical problem.
- Unscheduled medical care for a test subject that could be related to the research test.
- Close calls.
- Safety hazards.
- Safety or health concerns.
- Cases of non-compliance with federal regulations, NASA policies, or IRB approvals for human subject research.

4.7.2 The test subject shall notify the PI of any accident, injury, illness, changes in their health condition, hazards, safety concerns, or health concerns. If the test subject is not able to contact the PI or is not fully satisfied with the response of the PI, he or she should contact the LaRC Safety Office at (757) 864-7233 and/or the LaRC IRB Chairperson.

4.7.3 PIs shall:

a. Immediately report emergencies and/or obtain appropriate medical attention by calling 911 from any LaRC phone or 864-2222 from a cellular phone.
b. Report the event to the LaRC Safety Office at extension 47233.
c. Inform the LaRC IRB Chairperson.

4.7.4 The LaRC Safety Office shall:

a. Provide an initial response and assessment of the situation.
b. Notify LaRC and NASA Headquarters officials in accordance with established policies and protocols.
c. Initiate an investigation or inquiry, if appropriate.
d. Notify the LaRC IRB Chairperson.
e. Notify the Chief Health and Medical Officer at NASA Headquarters as specified in NPR 7100.1.

4.7.5 The LaRC IRB Chairperson shall:

a. Determine whether to issue an immediate suspension of the research.
b. Notify the Chief Health and Medical Officer at NASA Headquarters as specified in NPR 7100.1.
c. Promptly schedule a meeting of the LaRC IRB to review the circumstances surrounding the reported event.
d. Convene the LaRC IRB for a review of the unexpected event and a decision on whether the research should be suspended or terminated.

5. Reviewing Research Involving Human Subjects
LaRC IRB

5.1 LaRC IRB Charter

5.1 The LaRC IRB Charter is defined in LAPD 1150.2, “Boards, Panels, Committees, Councils, and Teams.”

5.2 LaRC IRB Authority

5.2.1 The LaRC IRB will have the full authority prescribed by 14 CFR 1230, NPD 7100.8, and NPR 7100.1. The LaRC IRB shall have the authority to approve, disapprove, or require changes in proposed experiments involving human subjects, and to suspend or cancel the approval of research activities that do not comply with previous approvals, have not been approved, or have exhibited the potential to harm anyone.

5.2.2 As conditions warrant, the LaRC IRB will submit reports or relevant recommendations to LaRC line management, the LaRC Executive Safety Council, and the Chief Medical and Health Officer at NASA Headquarters.

5.3 LaRC IRB Membership

5.3.1 The composition of the LaRC IRB will comply with the requirements stated in 14 CFR 1230.107 and NPR 7100.1.

5.3.2 The LaRC IRB will consist of at least seven members with non-consecutive 3-year terms.

5.3.3 In addition to the requirements of 14 CFR 1230.107 and NPR 7100.1, the LaRC IRB will have members with the following skills, expertise, or affiliation:

- A Medical Doctor.
- A Lawyer.
- A Scientist or Engineer.
- A pilot with formal test pilot school training or a current NASA research pilot.
- An Industrial Hygienist or Safety Engineer.
- The LaRC Occupational Health Officer or an employee of the Office of Human Capital Management.
- An employee of the Office of Chief Counsel.
- An employee of the Safety and Mission Assurance Office.
- A member with no other affiliation with NASA.
- A member representing the population from which research test subjects are chosen.

5.3.3.1 A single member may fulfill more than one of these requirements.

5.3.3.2 If suitable members are not available from within the LaRC civil service staff, then non-NASA personnel shall fill the membership.

5.3.4 The members of the LaRC IRB are listed in LAPD 1150.2.

5.3.5 The LaRC IRB may enlist input and advice from technical experts to supplement the knowledge of its members. LaRC line management shall support the LaRC IRB in obtaining any needed expertise. Technical experts may participate in LaRC IRB discussions, but shall not vote as a member of the LaRC IRB.

5.4 LaRC IRB Reviews

5.4.1 This document places research involving human subjects into one of four categories. LaRC IRB review of these four categories of research is described below.

5.4.1.1 Category 1 - Research that is conducted using LaRC personnel, facilities, or equipment.
The LaRC IRB shall review this research.

5.4.1.2 Category 2 - Research that is funded by LaRC, but conducted solely using personnel, facilities, or equipment of another institution.

5.4.1.2.1 For research involving human test subjects that is conducted solely by another institution and does not involve any NASA personnel, equipment, or facilities, the general practice will be to accept the governance of the local Institutional Review Board (the IRB of the institution conducting the research).

5.4.1.2.2 For cases that pose exceptional risk or where there is no local Institutional Review Board, the LaRC IRB will review the proposed experiment.

5.4.1.2.3 When a Technical Monitor initiates procurement action for a grant/contract, he/she will also forward a copy of the procurement documentation to the LaRC IRB Secretary.

5.4.1.2.4 The IRB Chairperson or Vice-Chairperson will screen each new funded NASA contract or grant that includes the use of human research subjects prior to its award. The screening will determine whether the research experiment will be referred to the LaRC IRB for review and approval. The screening will also assure that the contract/grant language contains the following provisions:

- Requires adherence to 14 CFR 1230 and the applicable elements of NPD 7100.8D, NPR 7100.1, and this LPR.
- Requires that Minutes of local IRB meetings related to this research experiment be forwarded to the LaRC Technical Monitor and the LaRC IRB Secretary.
- Explicitly states an IRB must review and approve the research experiment prior to the recruitment or involvement of any human test subjects.

5.4.1.2.5 The IRB screening official will document the results of the screening. One copy will be retained in the IRB files. Two copies will be forwarded to the grant/contract Technical Monitor. The Technical Monitor will forward a copy to the assigned Procurement official.

5.4.1.2.6 The Contracting Officer or Procurement Official shall not award the contract or grant until they have received IRB documentation affirming that an IRB screening or an IRB review has been completed.

5.4.1.2.7 A summary of all screening activities will be presented at the next meeting of the LaRC IRB.

5.4.1.3 Category 3 - Cooperative research that is conducted using both LaRC personnel, facilities, or equipment and personnel, facilities, or equipment from another institution.
Both the LaRC IRB and the IRB of the other institution involved with the research shall review cooperative research tests.

5.4.1.4 Category 4 NASA Research involving human subjects conducted aboard in-flight aircraft. This research includes activities funded by LaRC or activities involving LaRC personnel, aircraft, or equipment.
The Johnson Space Center IRB shall review this category of research. (The Johnson Space Center IRB serves as the NASA Flight IRB that is specified in NPR 7100.1, Chapter 6.) The PI shall contact the Johnson Space Center IRB to arrange for this review. Contact information for the Johnson Space Center IRB can be obtained from the Chairperson or Secretary of the LaRC IRB. (See LAPD 1150.2 for the names of these LaRC IRB members.). The LaRC IRB will support or assist the Johnson Space Center IRB upon request.

5.5 LaRC IRB Meetings

5.5.1 Meetings will be called by the LaRC IRB Chairperson. The LaRC IRB Secretary or Chairperson will provide notification to all LaRC IRB members and other invited participants. A copy of the application for LaRC IRB approval and the proposed Informed Consent Statement shall be distributed to LaRC IRB members prior to a meeting, whenever practical.

5.5.2 The PI (and other cognizant personnel) shall be encouraged to attend the LaRC IRB meeting to describe the research and answer questions. If the PI's physical presence is not practical, the use of videoconference or teleconference shall be explored to gain their participation.

5.5.3 Formal reviews will be conducted at a meeting where a majority of the LaRC IRB members are present. At least one member whose primary role/expertise is in a nonscientific area must also be present.

5.6 Decisions and Criteria For Approval

5.6.1 A formal action or decision of the LaRC IRB requires a positive vote by a majority of the members present. A quorum shall consist of a majority of the IRB members and include at least one member whose primary interest or concerns are in nonscientific areas.

5.6.2 Members who have involvement with or conflict of interest with research being reviewed by the LaRC IRB shall declare and explain their situation at the beginning of the LaRC IRB meeting. These members are encouraged to participate in the review by providing relevant information to the Board to ensure it has a complete understanding of the research being reviewed. Members with a conflict of interest shall not participate in the Board's deliberations nor vote on the matter at hand.

5.6.3 The criteria for LaRC IRB approval of human subject research are contained in CFR 1230.111 and NPR 7100.1 - Chapter 10.

5.6.4 The LaRC IRB shall decide whether: (a) projects require monitoring or review more often than annually; and (b) projects require verification from sources other than the PIs that no material changes have occurred.

5.6.5 The LaRC IRB will use the checklist provided in Appendix C to guide their review and decision process.

5.6.6 If the LaRC IRB decides to disapprove a proposed research activity, the reasons for the decision shall be included in the minutes of the LaRC IRB meeting. The PI shall be given a subsequent opportunity to respond to the LaRC IRB either in person or in writing.

5.7 Informed consent

5.7.1 The LaRC IRB shall review proposed Informed Consent Statements to verify the content conforms to the requirements of 14 CFR 1230.116 and NPR 7100.1 and the document uses language and terminology that can be clearly understood by the test subjects. The proposed research and the associated Informed Consent Statement shall not be approved until the LaRC IRB's legal advisor has reviewed and concurred with the content of the Informed Consent Statement.

5.7.2 If the LaRC IRB's legal advisor is not available and a decision is needed prior to the anticipated availability, the LaRC IRB Chairperson shall have another member of the LaRC Office of Chief Counsel provide the required review and concurrence for Informed Consent Statements.

5.8 Expedited Review

5.8.1 Expedited reviews may be used for the situations involving minimal risk to human subjects as specified in 14 CFR 1230 and NPR 7100.1. (See Appendix C of NPR 7100.1 for a list of types of research activities that may be reviewed by an expedited review.) Expedited reviews may also be used to review minor changes in previously approved research during the period for which approval was authorized. The LaRC IRB Chairperson may elect to convene a LaRC IRB meeting to review a proposal that meets the criteria for an expedited review.

5.8.2 Before initiating an expedited review, the LaRC IRB Chairperson shall determine that the proposal meets the allowable conditions specified in 14 CFR 1230 and NPR 7100.1. The LaRC IRB Chairperson shall select one or more LaRC IRB members to conduct the expedited review. The LaRC IRB legal advisor shall also review and concur with the Informed Consent Statement. The review and approval shall be documented similar to regular meetings. Copies shall be distributed to all LaRC IRB members, the PI, and the Chair and Secretary of the Executive Safety Council. If the LaRC IRB's designated reviewer feels that the proposal should be disapproved, a LaRC IRB meeting shall be held to review and determine the disposition.

5.9 Review of Simulators

5.9.1 The LaRC IRB shall review human used ground-based simulators and determine the potential risks of the simulator operations to the research subjects. The LaRC IRB shall make one of the following determinations: (a) some or all of the simulator operations will be exempt from further LaRC IRB review and approval; (b) some or all of the simulator operations will be handled by an expedited review; (c) some or all of the simulator operations will require a full LaRC IRB review; (d) the simulator shall not be used for human subject research; or (e) changes to the simulator are required before it can be used for human subject research.

5.10 Modifications

5.10.1 The LaRC IRB shall review and approve proposed modifications or changes to tests, procedures, and Informed Consent Statements before they can be implemented.

5.11 Unexpected Events, Safety Concerns, or Non-Compliances

5.11.1 The LaRC IRB shall review reports of unexpected events, safety concerns, and non-compliances. The IRB will invite the PI and other parties involved with the reported event to participate in the meeting and supply relevant information. The IRB shall review the circumstances surrounding the reported event and decide whether the research should be suspended or terminated. The IRB has the authority to require that changes be made to the research protocol or procedures to assure the safety and health of participants.

5.12 Suspension or Termination of Approved Research

5.12.1 If the LaRC IRB decides to suspend or terminate research that it has previously approved, then it shall document the decision and the supporting rationale. A copy of the document shall be promptly distributed to the PI, the associated Organizational Unit Manager, the Safety Manager, and the Authorized NASA Official as specified in NPD 7100.8. Copies shall also be sent to the Chair and Secretary of the Executive Safety Council and all members of the LaRC IRB.

5.12.2 Research that has been suspended or terminated by decision of the LaRC IRB shall not be resumed until a subsequent review and approval by the LaRC IRB.

5.13 IRB Meeting Minutes

5.13.1 The LaRC IRB Secretary will generate minutes of all LaRC IRB meetings. The content of meeting minutes shall comply with the requirements of NPR 7100.1, paragraph 5.1.2. Copies of the minutes shall be distributed in accordance with the requirements stated in LAPD 1150.2. It is permissible to distribute minutes electronically.

5.14 IRB Records

5.14.1 LaRC IRB records will be maintained in accordance with the requirements of 14 CFR 1230.115 and NPR 7100.1. IRB records shall be retained for 3 years beyond the last IRB action on a specific research proposal or specific issue. The LaRC IRB records will be filed and maintained by the LaRC IRB Secretary. It is permissible to retain records electronically.

5.14.2 The LaRC IRB shall retain the following documents for each proposed research test it reviews:

- The Application for IRB Review of Human Subject Research.
- The presentation material used at the LaRC IRB meeting.
- The approved version of the Informed Consent Statement.
- The completed checklist.

- The meeting minutes.
- Any other relevant documents.

5.15 Multiple Project Assurance Document and Annual Reports

5.15.1 The LaRC IRB Secretary will compile updates to the LaRC Multiple Project Assurance Document. After review and concurrence by the LaRC IRB, the LaRC IRB Secretary will send the document to NASA Headquarters in accordance with NPD 7100.8. The document will be routed through the LaRC Safety and Mission Assurance Office.

5.15.2 The LaRC IRB Secretary will compile a LaRC annual report on IRB activities and research involving human subjects as required by NPD 7100.8. The report will be routed through the LaRC Safety and Mission Assurance Office and sent to NASA Headquarters in accordance with NPD 7100.8. A copy of the report will be sent to all members of the LaRC IRB, the Director of the Safety and Mission Assurance Office, and the Chairperson of the Executive Safety Council.

6. Compliance Oversight and Audits

6.1 Oversight of the safety and health aspects of human subject research and the operation of the LaRC IRB will be provided by:

- Periodic audits conducted by OSHA under the Voluntary Protection Program.
- Periodic safety and health audits conducted by NASA Headquarters, Office of Safety and Mission Assurance.
- Ad-hoc reviews or audits conducted by the NASA Headquarters, Chief Health and Medical Officer.
- Operations of the LaRC Executive Safety Council.
- The LaRC Safety and Mission Assurance Office.
    - By routine safety and health audits.
    - By routine industrial hygiene audits.
    - By routine fire safety audits.
    - Through participation of an employee of the Office as a member of the LaRC IRB.

Appendix A

Outline
of
Application for IRB Review of Human Subject Research

NASA Langley Research Center
Institutional Review Board (IRB)
Application for Review of Human Subject Research

An electronic copy of this information (in Microsoft Word format)
may be obtained from the LaRC IRB Secretary or the LaRC IRB Chairperson.

The following information should be included in proposals submitted to the LaRC IRB. Address each topic. If a topic is not applicable, denote with "N/A."

1. **Title of Research Experiment**

2. **Investigators and Qualifications**
   2.1 List the PI(s), person(s) that will supervise the experiment and interact with test subjects, and other key personnel. Note the organizational affiliation of each person.

   2.2 Provide contact information for all parties listed.

   2.3 Briefly note the qualifications, training, and experience of the parties listed.

3. **Other Reviews**
   3.1 List any other reviews of this proposed experiment (scientific reviews, Institutional Review Board reviews, etc.). Note the associated recommendations, decisions, or conclusions from these reviews; or provide copies of minutes from the reviews.

4. **Abstract**
   4.1 Provide a brief abstract (500 words or less) of the proposed experiment.

5. **Purpose and Benefits**
   5.1 Describe the purpose of the experiment.

   5.2 Describe the potential specific benefits that may accrue to individual test subjects. Describe the potential specific benefits to others. Identify the groups or segments of society that will benefit.

6. **Test Subjects**
   6.1 Describe the rationale for using human subjects in this research.

   6.2 What population will test subjects be drawn from (general public, pilots, NASA employees, contractor personnel, other)?

   6.3 Provide additional information on the test subject population (organizational affiliation, skills, expertise, age, gender, race, etc.).

6.4 How many test subjects will be used? How many males? How many females? What age range?

6.5 Describe the rationale for using the proposed participant population.

6.6 How are test subjects chosen for participation in the experiment? What provisions are used to assure that subjects are equitably chosen?

6.7 Describe how test subjects will be recruited. Supply a copy of sign-up sheets, newspaper advertisements, announcements, etc.

6.8 Does this experiment use test subjects whose ability to give informed and/or voluntary consent may be in question? If so, describe the issue and explain in detail the procedures to be employed to ensure their protection.

6.9 Note the duration of each test subject's participation in the experiment.

6.10 Note the amount and type of compensation that will be provided to test subjects (payment, stipend, travel expenses, other).

6.11 Identify the source (Federal or state compensation acts and insurance) and general description of compensation, if any, to be received by a test subject or the test subject's legally authorized representative in the event of injury or death. (Assistance in obtaining this information may be obtained from the LaRC Office of Chief Counsel or the LaRC Office of Human Capital Management.)

6.12 Note any penalties associated with not participating in the experiment or failing to complete the agreed upon activities.

7. Description of Experiment

7.1 Schedule

List the expected start and completion dates for the experiment.

7.2 Roles of Research Team Members

Describe the roles of each of the investigators and other key personnel.

7.3 Collaboration

Note whether the experiment is being conducted in association or collaboration with any other department, agency, or organization (public or private). If so, identify the organizations and describe the collaboration and plans for sharing data.

7.4 Information Privacy

Describe the information that will be collected about each test subject and how private information will be protected.

7.5 Experimental Protocol

7.5.1 Describe the experimental procedures that will be followed. Submit copies of research protocols, questionnaires that test subjects are required to complete; plus copies of any instructions and debriefing information.

7.5.2 Will deliberate deception of test subjects be involved as part of this experiment? If so, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.

7.5.3 Will there be any deviation from the practice of complete disclosure and explanation of the experimental procedures during the debriefing? If so, explain the justification for the exception.

7.6 Equipment and Facilities

7.6.1 Identify the location and facility where the experiments will be conducted.

7.6.2 Identify equipment that will be used during the experiment.

7.6.3 Describe any equipment that will be used to monitor or measure the test subject's health or condition.

8. Hazard Analysis and Safety Precautions

8.1 Describe and assess any potential risks – physical, psychological, social, or economic – and assess the likelihood and seriousness of such risks associated with the experimental procedures. If methods of research create potential risks, describe any other alternatives considered, and why they will not be used.

8.2 Identify any test conditions that may pose a risk to the test subjects while participating in the proposed research

8.3 Identify any pre-existing medical or mental health conditions that may pose an increased risk to the test subjects while participating in the proposed research.

8.4 Describe the safety features, equipment, practices, and procedures that will be used to mitigate hazards and protect test subjects during this experiment.

8.5 Describe any procedures that will be used to monitor and safeguard the health of test subjects. Identify any medical care that will be available or present on-site during the tests. If a physician will be on call during the test, note where the physician will be located. Describe any medical examinations that will be performed before the test, during the test, or after the test.

8.6 Describe any procedures that will be used for dealing with emergencies.

9. Inconveniencies or Discomforts

9.1 Note any aversive or painful procedures that will be employed (e.g., shock, the threat of shock or punishment, experimentally induced stress, etc.). If so, specify and justify in detail. If aversive or painful procedures pose no risk, explain why.

10. Screening

10.1 Will the study utilize any pre-test or post-test screening (questionnaires or medical exams) of test subjects to determine their appropriateness for inclusion in the study or to protect their health and safety? If so, describe the screening process, the screening criteria, and its rationale. Attach a copy of any screening questionnaires or the description of any medical exams.

11. Ethical Issues

11.1 Note any ethical issues relating to this research. Identify any financial interest that the PI or other investigators have in the research study. Include any benefits that these individuals will derive from knowledge or products being developed by the study.

12. Informed Consent

12.1 Describe the procedure that will be used for obtaining informed consent.

12.2 Supply a copy of the Informed Consent Statement plus any associated briefing or handout material.

13. Expedited Review

13.1 Is this an application for Expedited Review?

13.2 If yes, verify it meets the criteria listed in 14 CFR 1230.110 and Appendix C of NPR 7100.1. Identify the specific item(s) in Appendix C that applies to this application.

13.3 Identify similar experiments and the dates they were previously approved by the LaRC IRB.

13.4 Describe the changes/differences between what was previously approved and what is being requested by this application.

14. Identify any similar experiments, procedures, or facilities that have been previously approved by the LaRC IRB.

[ ] Visual Flight Rules Flight Simulator
[ ] Instrument Flight Rules Simulator
[ ] Desktop Simulator
[ ] Air Traffic Control Laboratories (AATT)
[ ] Visual Imaging Simulator for Transport Aircraft Systems (VISTAS) I
[ ] VISTAS III
[ ] Cockpit Motion Facility, Generic Flight Deck (GFD)
[ ] Cockpit Motion Facility, Integration Flight Deck (IFD)
[ ] Cockpit Motion Facility, Research Flight Deck (RFD)
[ ] Performance and Behavioral Measures
[ ] Electroencephalogram / Event-Related Potentials
[ ] Electrocardiogram
[ ] Electrodermal Activity
[ ] Galvanic Skin Response
[ ] Blood pulse, skin temperature
[ ] Eye Tracking
[ ] Small Anechoic Chamber
[ ] Aircraft Interior Acoustic Simulator
[ ] Exterior Effects Room
[ ] Sonic Boom Simulator
[ ] Other _____

15. List any documents that accompany this application.

Appendix B

Information for LaRC Informed Consent

Information on LaRC Informed Consent Statements

Informed consent shall be documented by the use of a written consent statement approved by the LaRC IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

The written consent statement shall embody three parts:
1. The elements required by 14 CFR 1230 and NPR 7100.1.
   (A summary of those elements is listed below.)
2. Safety text for research involving LaRC personnel, facilities, or equipment.
3. Statement of Consent.

Summary of the elements required by 14 CFR 1230 and NPR 7100.1

Basic Elements of Informed Consent

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others, which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subjects will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation will be provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. Identification of a point of contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
9. A statement that any subject who has a concern about protocol violations or their safety, health, or welfare, may request a meeting with the LaRC IRB.

Supplemental Elements of Informed Consent
When appropriate, one or more of the following supplementary elements of informed consent shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) that are currently unforeseeable.
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.
3. Any additional costs to the subject that may result from participation in the research.
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of research which may relate to the subject's willingness to continue participation will be provided to the subject.
6. The approximate number of subjects involved in the study.
7. Any collective impact of multiple protocols, if applicable.
8. Disclosure of any financial interest the PI has in the study, including benefits that the PI will derive from information or products being developed by the study.

The following safety text shall be included in Informed Consent Statements for human subject research that involves LaRC personnel, facilities, or equipment.
(This text may be tailored to appropriately address individual test situations.)

Safety
As a voluntary test subject participating in this research, I understand that:
1. NASA is committed to ensuring my safety, health, and welfare plus the safety and health of all others involved with the research.
2. I should report any accident, injury, illness, changes in my health condition, hazards, safety concerns, or health concerns to [insert name and phone number]. If I am unable to reach the above named individual or am not satisfied with their response, I should contact the LaRC Safety Office at (757) 864-7233 or the Chairperson of the LaRC IRB, [insert name and phone number].
3. If I detect any unsafe condition that presents an imminent danger to myself, or others, I have the right and authority to stop the activity or test. In such cases the PI and associated research personnel will comply with my direction, stop the activity, and take action to address the imminent danger.

Statement of Consent

I certify that I have read and fully understand the explanation of procedures, benefits, and risks associated with the research herein, and I agree to participate in the research described herein. My participation is given voluntarily and without coercion or undue influence. I understand that I may discontinue participation at any time. I have been provided a copy of this consent statement. If I have any questions or modifications to this consent statement, they are written below:

_____	_____
Participant's Signature	Witness's Signature
_____	_____
Participant's Name [printed]	Witness's Name [printed]
_____	_____
_____	_____
Participant's Address	Witness's Address

_____
Participant's Phone

_____
Participant's Date of Birth

_____
Date

Appendix C

LaRC Institutional Review Board Checklist

LaRC Institutional Review Board Checklist

Experiment Title: _____ Date:_____

Requirements for approval:
_____ Risks to subjects have been minimized.
_____ Risks to subjects are reasonable in relation to anticipated benefits.
_____ Selection of subjects is equitable. Vulnerable populations are not unduly at risk.
_____ Appropriate safeguards have been included to protect the rights, welfare, and safety of any test subjects that are likely to be vulnerable to coercion or undue influence.
_____ Voluntary informed consent will be sought.
_____ Informed consent is properly documented. The description of the experiment and risks is clear, accurate, and complete.
_____ The IRB's legal advisor has reviewed the informed consent statement and concurred with its contents.
_____ Experimental procedures include adequate provisions for monitoring and assuring the health and safety of test subjects.
_____ Adequate provisions exist for protecting the privacy of information about test subjects and the confidentiality of data.
_____ Any ethical issues and financial conflicts of interest involving the Investigators have been addressed.
_____ The Investigators have completed the required training.

Considerations:
_____ Will a member of the IRB participate in: (a) a dry-run or demonstration of the test protocol; or (b) witness testing of the first test subject?
_____ Will the IRB monitor/observe testing or conduct future reviews of this experiment? If yes, define: _____.
_____ Has the IRB visited the test facility and viewed the test equipment?
_____ Have representatives of the IRB inspected the test facility and test equipment?
_____ Have the facility and/or test equipment been previously approved by the IRB or used in experiments previously approved by the IRB?

IRB Action
[ ] Proposal approved as presented
[ ] Proposal approved pending incorporation of specific IRB recommended changes*
[ ] Proposal tabled pending response to IRB concerns or request for more information*
[ ] Proposal disapproved*

Vote: For_____ Against_____ Abstained_____

* Note information on next page

Specific Changes Recommended by the IRB

IRB Concerns

Additional Information Requested by the IRB

Reason(s) for Disapproval